

Joseph R. Saveri (State Bar No. 130064)  
Nicomedes Sy Herrera (State Bar No. 275332)  
Jiamie Chen (*pro hac vice* application to be submitted)  
Kevin Rayhill (State Bar No. 267496)  
Kyla Gibboney (State Bar No. 301441)  
JOSEPH SAVERI LAW FIRM, INC.  
601 California Street, Suite 1000  
San Francisco, California 94108  
Telephone: (415) 500-6800  
Facsimile: (415) 395-9940  
Email: jsaveri@saverilawfirm.com  
nherrera@saverilawfirm.com  
jchen@saverilawfirm.com  
krayhill@saverilawfirm.com  
kgibboney@saverilawfirm.com

*Attorneys for Plaintiffs*

UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA  
SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA; STATES  
OF CALIFORNIA, COLORADO,  
CONNECTICUT, DELAWARE, FLORIDA,  
GEORGIA, HAWAII, ILLINOIS, INDIANA,  
IOWA, LOUISIANA, MARYLAND,  
MICHIGAN, MINNESOTA, MONTANA,  
NEVADA, NEW HAMPSHIRE, NEW  
JERSEY, NEW MEXICO, NEW YORK,  
NORTH CAROLINA, OKLAHOMA, RHODE  
ISLAND, TENNESSEE, TEXAS, VERMONT,  
AND WASHINGTON; THE  
COMMONWEALTHS OF  
MASSACHUSETTS AND VIRGINIA; AND  
THE DISTRICT OF COLUMBIA,

*ex rel.* ZACHARY SILBERSHER,

Plaintiffs,

v.

JANSSEN BIOTECH, INC., JANSSEN  
ONCOLOGY, INC., JANSSEN RESEARCH &  
DEVELOPMENT, LLC, and JOHNSON &  
JOHNSON,

Defendants.

**FILED**

DEC 21 2017

SUSAN Y. SOONG  
CLERK, U.S. DISTRICT COURT  
NORTHERN DISTRICT OF CALIFORNIA

**UNDER SEAL**

Case No.:

**COMPLAINT FOR VIOLATIONS OF:**

1. **THE FEDERAL FALSE CLAIMS ACT, 31 U.S.C. §§ 3729-3733; AND**
2. **THE FALSE CLAIMS ACTS OF THE PLAINTIFF STATES, COMMONWEALTHS, AND THE DISTRICT OF COLUMBIA**

***QUITAM ACTION FILED  
IN CAMERA AND UNDER SEAL***

**DO NOT PLACE IN PRESS BOX  
DO NOT ENTER ON PACER**

**JURY TRIAL DEMANDED**

Plaintiff-Relator Zachary Silbersher (“Relator”), through his attorneys the Joseph Saveri Law Firm, Inc., on behalf of the United States of America; the States of California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, Vermont, and Washington; the Commonwealths of Massachusetts and Virginia; and the District of Columbia (the foregoing states, commonwealths and the District of Columbia collectively, “the Plaintiff States”), for his Complaint against defendants Janssen Biotech, Inc. (“Janssen Biotech”), Janssen Oncology, Inc. (“Janssen Oncology”), Janssen Research & Development, LLC (“Janssen R&D”), and Johnson & Johnson (“J&J”) (collectively, “Janssen” or “Defendants”), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

## **I. INTRODUCTION**

### **A. Overview of Defendants’ False Claims**

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the Plaintiff States arising from Defendants’ violations of the federal False Claims Act, 31 U.S.C. §§ 3729–3733 (the “Act” or “Federal FCA”); and the false claims acts of the Plaintiff States (the “State FCAs”).

2. Defendants manufacture, sell, and distribute Zytiga® (abiraterone acetate), which doctors widely prescribe to patients with metastatic castration-resistant prostate cancer (mCRPC). In the United States, a one-month prescription of Zytiga typically costs over \$9,000. Zytiga is covered by Medicare, Medicaid, and other government programs. The typical patient takes Zytiga for twelve to eighteen months.

3. Defendants make over \$2 billion each year selling Zytiga. Over \$1 billion of such sales are made in the United States. Approximately 80% of prostate cancer patients in the United States are covered by Medicare. Plaintiff States’ Medicaid programs also cover Zytiga. Additionally, the United States Government purchases Zytiga through numerous programs, including, without limitation, the Veterans’ Administration. Therefore, government funds pay a significant portion —

1 indeed, the large majority—of Zytiga’s annual sales in the United States. Government funds  
2 therefore disproportionately bear the burden of Zytiga’s elevated, monopolist prices.

3 4. The chemical compound patent covering Zytiga—U.S. Patent No. 5,604,213 (the  
4 “’213 Patent”)—expired on December 13, 2016. Defendants knew that at least fourteen generic  
5 manufacturers were ready, willing, and able to introduce generic competition to Zytiga when the ’213  
6 Patent expired. Such generic competition would have reduced the price of abiraterone acetate by at  
7 least 80%, and Defendants would have reasonably expected to lose 90% or more of Zytiga’s market  
8 share. To protect their monopolist profits for abiraterone acetate—which patients dying of mCRPC  
9 desperately need—Defendants fraudulently obtained a patent to block generic entry after the  
10 expiration of the ’213 Patent. The fraudulently obtained patent is U.S. Patent 8,822,438 (the ’438  
11 Patent).

12 5. Even though Defendants know the fraudulent ’438 Patent eventually will be  
13 invalidated, the delay caused by Defendants’ fraudulent course of conduct manipulating the  
14 regulatory structure for generic approval (described below) has allowed Defendants wrongfully to  
15 shield over \$1 billion in Zytiga revenue, most of it paid by federal and state government funds.

16 6. The Federal FCA and the State FCAs provide a mechanism for the federal and state  
17 governments to protect their health care funds from such unlawful predation. Relator brings this *qui*  
18 *tam* action to do so.

19 7. As set forth below, Defendants have knowingly presented, or caused to be presented,  
20 false or fraudulent claims for payment or approval by the United States Government and each of the  
21 Plaintiff States in connection with the sale of Zytiga (each, a “False Claim”). These False Claims  
22 include, without limitation: (a) claims for Medicare and Medicaid reimbursement for Zytiga  
23 prescriptions; and (b) claims for payment relating to government purchases of Zytiga under certain  
24 government healthcare programs, such as the Veterans’ Administration.

25 8. Defendants willfully made false and materially misleading statements to the United  
26 States Patent and Trademark Office (“Patent Office”) to fraudulently obtain the ’438 Patent, which  
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1 expires in 2027. The '438 Patent is being used by Defendants unlawfully to extend their monopoly in  
2 the sale of Zytiga and protect the market from generic competition.

3 9. Each and every False Claim for payment or reimbursement for Zytiga that Defendants  
4 submitted by (or caused to be submitted by) violated the Federal FCA and the respective State  
5 FCAs. Among other reasons, each False Claim was for payment based on an unlawfully elevated  
6 price for Zytiga contrary to Defendants' express or implied certification that the price of Zytiga was  
7 not unlawfully elevated, maintained, or stabilized in violation of applicable law, including applicable  
8 antitrust laws. Moreover, Defendants made false, fraudulent, and misleading statements to the  
9 Patent Office in connection the submission of each False Claim because the price of Zytiga reflected  
10 in each False Claim was unlawfully elevated as a result of Defendants' false, fraudulent, and  
11 misleading statements to the Patent Office.

12 10. In its submissions to the Patent Office, Defendants claimed that approximately 37,000  
13 patients with mCRPC were treated per month in 2013. Of this total mCRPC population, less than  
14 one-third (approximately 10,000) were chemo-refractory patients (*i.e.*, had previously undergone  
15 chemotherapy), and the remaining were chemo-naïve patients. Defendants also stated that by April  
16 2013, Zytiga commanded approximately 57% of the chemo-refractory market, and nearly 20% of the  
17 remaining chemo-naïve market.

18 11. According to the Centers for Medicare & Medicaid Services ("CMS"), a federal  
19 agency within the United States Department of Health and Human Services ("DHHS"), in 2015,  
20 Medicare reimbursed 81,058 prescriptions for Zytiga for over \$637 million. This implies that  
21 Medicare, on average, reimbursed \$7,861 for every Zytiga prescription in 2015.

22 12. Upon information and belief, the number of prescriptions written for Zytiga in 2017 is  
23 higher than it was in 2015, even though the prices have gone up. Thus, it is reasonable to infer that  
24 Defendants submitted or caused to be submitted at least 6,750 False Claims to Medicare every  
25 month in 2017 relating to Zytiga.

26 13. Zytiga is also covered by Medicaid programs for the Plaintiff States, making payments  
27 relating to Zytiga purchases and reimbursements a substantial burden on Medicaid funds. According  
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1 to CMS, various Plaintiff States reimbursed 3,697 Zytiga prescriptions (many of which were written  
 2 and submitted in this District) from January 1 through April 30, 2017, for a total Medicaid  
 3 reimbursement of \$30,747,287.71. These data imply that Medicaid programs reimburse on average  
 4 over \$8,300 for every Zytiga prescription.

5 14. The United States Government also purchases Zytiga through government-funded  
 6 health programs, including, without limitation, Indian Health Services; Prison Health Services;  
 7 Veterans' Administration prescription drug purchases and reimbursements; Military Health System;  
 8 Defense Health Agency / TRICARE; Coast Guard; and the Federal Bureau of Prisons.

9 15. Each and every time that Defendants submitted, or caused to be submitted, any False  
 10 Claim for payment or reimbursement for Zytiga to the United States Government or any of the  
 11 Plaintiff States, Defendants violated the federal False Claims Act, 31 U.S.C. §§ 3729-3733 (the  
 12 "Federal FCA"), and the state false claims act of the respective Plaintiff State (each, a  
 13 "State FCA") in which such submission was made, as applicable.

14 16. As set forth herein, Defendants' actions alleged in this Complaint violate the Federal  
 15 FCA and the following State FCAs: The California False Claims Act, Cal. Gov't Code §§ 12650-  
 16 12656; Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310.; Connecticut  
 17 False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289; Delaware False Claims and Reporting Act,  
 18 Del. Code Ann. tit. 6, §§ 1201-1211; District of Columbia False Claims Act, D.C. Code §§ 2-381.01  
 19 to .09; Florida False Claims Act, Fla. Stat. §§ 68.081-.09; Georgia False Medicaid Claims Act, Ga.  
 20 Code Ann. §§ 49-4-168 to 168.6; Hawaii False Claims Act, Haw. Rev. Stat. §§ 661-21 to -31; Illinois  
 21 False Claims Act, 740 Ill. Comp. Stat. 175/1-175/8; Indiana False Claims and Whistleblower  
 22 Protection Act, Ind. Code §§ 5-11-5.5-1 to -18; Iowa False Claims Act, Iowa Code §§ 685.1-.7;  
 23 Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. §§ 46:437-440; Maryland  
 24 False Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611; Massachusetts False  
 25 Claims Act, Mass. Gen. Laws ch. 12, §§ 5A-5O; Michigan Medicaid False Claims Act, Mich. Comp.  
 26 Laws. §§ 400.601-.615; Minnesota False Claims Act, Minn. Stat. §§ 15C.01-.16; Montana False  
 27 Claims Act, Mont. Code Ann. §§ 17-8-401 to -413; Nevada statute concerning Submission of False  
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1 Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010-.250; New Hampshire Health  
 2 Care False Claims Law, N.H. Rev. Stat. Ann. §§ 167:58 to :61-e; New Jersey False Claims Act, N.J.  
 3 Stat. Ann. §§ 2A:32C-1 to -18; New Mexico Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1  
 4 to -15, and New Mexico Fraud Against Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14; New York  
 5 False Claims Act, N.Y. State Fin. Law §§ 187-194; North Carolina False Claims Act, N.C. Gen.  
 6 Stat. §§ 1-605 to -618; Oklahoma Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053-5053.7;  
 7 Rhode Island False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9; Tennessee Medicaid False Claims  
 8 Act, Tenn. Code Ann. §§ 71-5-181 to -185; Texas Medicaid Fraud Prevention Law, Tex. Hum. Res.  
 9 Code Ann. §§ 36.001-.132; Vermont False Claims Act, Vt. Stat. Ann. tit. 32, §§ 630-642; Virginia  
 10 Fraud Against Taxpayers Act, Va. Code §§ 8.01-216.1 to .19; and Washington State Medicaid Fraud  
 11 False Claims Act, Wash. Rev. Code §§ 74.66.005-.130.

## 12 **II. PARTIES**

13 17. The Relator Zachary Silbersher is a citizen of New York. Through his independent  
 14 investigation, Relator has uncovered non-public information supporting the claims set forth herein.  
 15 The Relator's independent research and investigation has generated information that is independent  
 16 of and materially adds to any publicly disclosed allegations and transactions.

17 18. Relator is an "original source" of information within the meaning of 31 U.S.C.  
 18 § 3730(e)(4)(B) and all applicable state statutes for the Plaintiff States. Relator has voluntarily  
 19 provided the information on which the allegations or transactions alleged herein are based to the  
 20 Government and the Plaintiff States before filing this action.

21 19. Relator seeks to recover all available damages, civil penalties, and other relief for  
 22 federal and state-law violations alleged herein. In particular, Relator sues to recover on behalf of the  
 23 United States Government and its various agencies administering federally funded health care  
 24 programs, including, without limitation, Medicare and Medicaid; Indian Health Services; Prison  
 25 Health Services; Veterans' Administration prescription drug purchases and reimbursements;  
 26 Military Health System; Defense Health Agency / TRICARE; Coast Guard; and the Federal Bureau  
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1 of Prisons; and (2) the Plaintiff States and their respective agencies administering State programs for  
2 prescription drug coverage, including, without limitation, Medicaid contributions.

3 20. Defendant Janssen Biotech, Inc., is a corporation organized and existing under the  
4 laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA  
5 19044. Janssen Biotech is a wholly-owned subsidiary of Johnson & Johnson ("J&J").

6 21. Defendant Janssen Oncology, Inc., is corporation organized and existing under the  
7 laws of Delaware, with its principal place of business at 10990 Wilshire Boulevard, Los Angeles, CA  
8 90024. Janssen Oncology is a wholly-owned subsidiary of J&J.

9 22. Defendant Janssen Research & Development, LLC, is a limited liability company  
10 organized and existing under the laws of the State of New Jersey, with its principal place of business  
11 at 920 Route 202 South, Raritan, New Jersey 08869. Janssen R&D is a wholly-owned subsidiary of  
12 J&J.

13 23. Defendant Johnson & Johnson ("J&J") is corporation organized and existing under  
14 the laws of the State of New Jersey, with its principal place of business of One Johnson & Johnson  
15 Plaza, New Brunswick, New Jersey 08933. J&J is the parent corporation of the Janssen entities and  
16 filed false, misleading, and fraudulent documents with the USPTO in connection with the '438  
17 Patent in concert with the other Defendants in furtherance of Defendants' collective efforts  
18 improperly to extend Defendants' monopoly in Zytiga (abiraterone acetate) and exclude generic  
19 competitors through the scheme alleged herein. Through its wholly-owned subsidiary Cougar  
20 Biotechnology, J&J also holds the rights to the '213 Patent, which originally protected Zytiga's  
21 chemical compound and expired in December 2016.

22 24. Defendants sell Zytiga in the United States pursuant to New Drug Application  
23 ("NDA") No. 202379, which has been approved by the United States Food and Drug  
24 Administration ("FDA").

25 25. Janssen Oncology owns all right, title, and interest in the '438 Patent, entitled  
26 "Methods and Composition for Treatment of Cancer," as issued by the United States Patent and  
27 Trademark Office on September 2, 2014.  
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1           26.     Janssen Biotech is the holder of NDA No. 202379. Janssen R&D works in  
2 collaboration with Janssen Biotech with respect to NDA No. 202379.

3     **III.    JURISDICTION AND VENUE**

4           27.     This Court has jurisdiction over the subject matter of this action pursuant to  
5 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. §§ 3730(b)(1) and 3732, the last of which  
6 specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and  
7 3730. In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state  
8 law claims.

9           28.     Under 31 U.S.C. § 3730(e), and under the comparable provisions of the Plaintiff State  
10 statutes, there has been no statutorily relevant public disclosure of the “allegations or transactions”  
11 in this Complaint. Moreover, whether or not such a disclosure had occurred, Relator would qualify  
12 as an “original source” of the information in this Complaint, even had such a public disclosure  
13 occurred. Relator has direct and independent knowledge of the information on which the allegations  
14 herein are based; such knowledge materially adds to any publicly disclosed allegations or  
15 transactions; and Relator voluntarily provided the information to the Government before filing this  
16 action and before any public disclosure of the allegations and transactions in this Complaint material  
17 to the false claims alleged herein.

18           29.     This Court has personal jurisdiction over each of the Janssen entities pursuant to  
19 31 U.S.C. § 3732(a), which authorizes nationwide service of process. Moreover, each of the Janssen  
20 entities maintain minimum contacts with the United States, and they all can be found in and transact  
21 business in this District.

22           30.     Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and  
23 31 U.S.C. § 3732(a) because Defendants can be found in and transact business in this District. At all  
24 times relevant to this Complaint, each of the Defendants regularly conducted substantial business  
25 within this District and made significant sales within this District. Moreover, numerous acts violating  
26 31 U.S.C. §§ 3729-3733 occurred in this District, and a substantial part of the events giving rise to the  
27 claims alleged herein occurred here. Finally, J&J; Janssen Research & Development, LLC; and, upon  
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1 information and belief, the other Defendant entities, maintain employees that regularly work in this  
2 District.

3 31. Many of the acts underlying the false claims allegations herein occurred in this  
4 District, and thousands of False Claims were submitted in this District relating to Zytiga sales made  
5 within this District.

#### 6 **IV. FEDERAL AND STATE-FUNDED HEALTH CARE PROGRAMS**

7 32. Government-funded health care programs cover medical services and prescriptions  
8 for one-third of the United States population.

##### 9 **A. Medicare**

10 33. Medicare is a federally-funded health insurance program primarily benefitting the  
11 elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted.

12 34. The Medicare program has four parts: Part A, Part B, Part C, and Part D. Medicare  
13 Part A ("Part A"), the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services  
14 and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan,  
15 covers the cost of services performed by physicians and certain other health care providers, both  
16 inpatient and outpatient, if the services are medically necessary and directly and personally provided  
17 by the provider. Medicare Part C covers certain managed care plans. Medicare Part D provides  
18 subsidized prescription drug coverage for Medicare beneficiaries.

19 35. Medicare provides benefits for patients being treated with Zytiga under Part D.

20 36. The Medicare program is administered through CMS at the DHHS.

##### 21 **B. Medicaid**

22 37. Medicaid is jointly administered by the United States and each of the separate states,  
23 including the Plaintiff States.

24 38. Individual state Medicaid programs are administered by each state, subject to  
25 oversight by the United States in accordance with statutes and regulations promulgated by the  
26 United States and the Secretary of the DHHS. Pursuant to these statutes and regulations, the United  
27 States provides financial assistance to each of the state Medicaid programs by providing each state  
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1 with financing equal to at least 50% of the costs incurred by the state Medicaid programs. In some  
 2 instances, the United States provides financing equal to as much as 75% of program costs incurred,  
 3 including the costs incurred for reimbursing providers for dispensing prescription drug products  
 4 (such as Zytiga) to Medicaid beneficiaries.

5 39. Each state Medicaid program obtains federal financial assistance by submitting  
 6 quarterly claims to the United States for federal financial assistance related to the costs incurred for  
 7 administering the state Medicaid programs.

### 8 **C. Other Government-Funded Health Programs**

9 40. The other major government-funded health programs—including Indian Health  
 10 Services; Prison Health Services; Veterans' Administration prescription drug purchases and  
 11 reimbursements; Military Health System; Defense Health Agency / TRICARE; Coast Guard; and  
 12 the Federal Bureau of Prisons—purchase significant amounts of Zytiga for their covered patients.

## 13 **V. THE REGULATORY STRUCTURE THAT DEFENDANTS MANIPULATED TO** 14 **BLOCK GENERIC COMPETITORS TO ZYTIGA**

### 15 **A. The Regulatory Structure for Approval of Generic Drugs**

16 41. Under the Federal Food, Drug, and Cosmetic Act (FDCA), a manufacturer must  
 17 obtain FDA approval to sell a new drug by filing a New Drug Application (NDA). 21 U.S.C. §§ 301-  
 18 392. An NDA must include submission of specific data concerning the safety and effectiveness of the  
 19 drug, and identify any patent that allegedly claims either the approved drug or approved methods of  
 20 use of the drug that could reasonably be asserted against a generic manufacturer that makes, uses, or  
 21 sells a generic version of the brand drug prior to the expiration of the listed patent(s). 21 U.S.C.  
 22 § 355(a), (b). When the FDA approves an NDA, it publishes the patents identified by the brand  
 23 manufacturer in a database called "Approved Drug Products with Therapeutic Equivalence  
 24 Evaluations," commonly known as the "Orange Book." Patents issued after NDA approval may be  
 25 listed in the Orange Book within thirty days of issuance. 21 U.S.C. § 355(b)(1), (c)(2).

26 42. The FDA relies completely on the brand manufacturer's truthfulness about patent  
 27 validity and applicability, because it does not have the resources or authority to verify the  
 28 manufacturer's patents were not procured through fraud. In listing patents in the Orange Book, the

1 FDA merely performs a ministerial act. Therefore, pharmaceutical companies that list patents in the  
2 Orange Book that they claim protect a particular drug have a duty to list only those patents they  
3 believe in good faith restrict generic entry.

4 **B. The Hatch-Waxman Amendments**

5 43. The Hatch-Waxman Amendments to the FDCA, enacted in 1984, simplified the  
6 regulatory hurdles for prospective generic manufacturers by eliminating the need for them to file  
7 lengthy and costly NDAs. *See* Drug Price Competition and Patent Term Restoration Act, Pub. L.  
8 No. 98-417, 98 Stat. (1984). A generic manufacturer seeking approval to sell a generic version of a  
9 brand drug may instead file an Abbreviated New Drug Application (“ANDA”). An ANDA relies on  
10 the scientific findings of safety and effectiveness included in the brand manufacturer’s original NDA.  
11 An ANDA must show that the generic drug contains the same active ingredient(s), dosage form,  
12 route of administration, and strength as the brand drug, and is absorbed at the same rate and to the  
13 same extent as the brand drug—that is, that the generic drug is pharmaceutically equivalent and  
14 bioequivalent (together, “therapeutically equivalent”) to the brand drug. *See generally* 21 U.S.C.  
15 § 355(j) *et seq.*

16 44. The FDCA and Hatch-Waxman Amendments operate on the principle that  
17 bioequivalent drug products containing identical amounts of the same active ingredients, having the  
18 same route of administration, dosage and form, and meeting applicable standards of strength, quality,  
19 purity and identity, are therapeutically equivalent and may be substituted for one another.  
20 Bioequivalence demonstrates that the active ingredient of the proposed generic drug is absorbed at  
21 the site of drug action to the same extent and for the same amount of time as the branded  
22 counterpart. 21 U.S.C. § 355(j)(8)(B). Thus, a generic drug is identical to a brand name drug in  
23 dosage, form, safety, strength, route of administration, and intended use.

24 45. Generic drugs that are therapeutically equivalent to their brand counterparts are given  
25 an “AB” rating by the FDA, allowing their substitution for the brand when a patient presents a  
26 prescription for the brand product.  
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46. Congress enacted the Hatch-Waxman Amendments to expedite the entry of generic competitors, thereby reducing healthcare expenses nationwide. As a result, generic drugs became an increasingly large part of prescription drug revenues, and a growing threat to brand name drug profits. In 1984, prescription drug revenue for brand and generic drugs totaled \$21.6 billion, with generic drugs accounting for 18.6% of total prescriptions. By 2013, total prescription drug revenue had climbed to more than \$329.2 billion, with generic drugs accounting for 84% of prescriptions. *See* IMS Institute for Healthcare Informatics, *Medicine and Shifting Costs of Healthcare* 30, 51 (2014).

**C. Paragraph I, II, III, and IV Certifications**

47. To obtain FDA approval of an ANDA, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any patents listed in the Orange Book. Under the Hatch-Waxman Amendments, a generic manufacturer's ANDA must contain one of four certifications for each Orange Book-listed patent:

- a. That no patent for the brand name drug has been filed with the FDA (a "Paragraph I certification");
- b. that the patent for the brand drug has expired (a "Paragraph II certification");
- c. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date (a "Paragraph III certification"); or
- d. that the patent for the brand drug is invalid or will not be infringed by the generic manufacturer's proposed product (a "Paragraph IV certification").

48. Because ANDAs with Paragraph I, II, or III certifications face no potential patent challenge, FDA approval of these ANDAs is relatively quick and expeditious.

49. However, when a generic manufacturer is forced to file a Paragraph IV certification because the Orange Book lists a drug that has not or will not expire by the time of the planned generic entry, the brand manufacturer is able trigger extensive regulatory delays that will block FDA approval of generic entry—potentially for many years.

50. When a generic manufacturer files a Paragraph IV certification, it must promptly



1 provide notice to the brand manufacturer. Filing an ANDA with a Paragraph IV certification gives  
2 rise to a cause of action for patent infringement regardless of the merits of the action. If the brand  
3 manufacturer initiates a patent infringement action against the generic filer within forty-five days of  
4 receiving notification of the Paragraph IV certification (“Paragraph IV Litigation”), the FDA will  
5 not grant final approval to the ANDA until the earlier of (a) the passage of thirty months from the  
6 notification date, or (b) the issuance of a decision by a court that the patent is invalid or not infringed  
7 by the generic manufacturer’s ANDA. Until one of those conditions occurs, the FDA may grant  
8 “tentative approval,” but cannot authorize the generic manufacturer to go to market with its  
9 product. Tentative approval means the ANDA would be ready for final approval but for the 30-  
10 month stay. As a practical matter, the initiation of a patent infringement action provides the brand  
11 manufacturer with the equivalent of an automatic 30-month injunction that prevents the generic  
12 manufacturer from releasing a competing generic product, regardless of the merits of the  
13 infringement action.

14 **D. The Economic Benefits of Blocking Generic Entry, Even When Frivolous**

15 51. Therapeutically equivalent (or AB-rated) generic drugs contain the same active  
16 ingredient, and are determined by the FDA to be just as safe and effective, as their branded  
17 counterparts. The only material difference between generic drugs and branded drugs is their price:  
18 when multiple generic drug manufacturer competitors enter the market for a given branded drug,  
19 generic drugs cost, on average, 80%-85% lower than the branded drug prior to generic entry.  
20 Moreover, the Federal Trade Commission (FTC) estimates that about one year after market entry, a  
21 generic drug takes over 90% of the branded drug’s unit sales.

22 52. When multiple generics enter the market, competition accelerates, and prices drop to  
23 their lowest levels. Competition from several generic sellers drives drug prices down toward marginal  
24 manufacturing costs.

25 53. In the majority of states, pharmacists may (and in some cases are required) by statute  
26 or regulation to substitute a therapeutically equivalent generic drug with a brand-name drug—even  
27 when a prescription lists a brand-name drug—unless the prescription specifically prohibits such  
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1 substitution. The Office of Inspector General of the DHHS has determined that generic drugs are  
2 dispensed 89% of the time when generic substitutes were available.

3 54. Launched in 2011, Zytiga's annual sales have reached approximately \$2 billion, with  
4 sales in the second quarter of 2016 of approximately \$600 million. In the United States, annual sales  
5 in 2015 and 2016 were approximately \$1.05 billion and \$1.09 billion, respectively.

6 55. Zytiga was originally approved by the FDA in the chemo-refractory mCPRC market  
7 on April 28, 2011, and its FDA-approved exclusivity expired no later than April 28, 2016. Because at  
8 least fourteen generic manufacturers were willing and able to enter the market when the '238 Patent  
9 expired in December 2016, Defendants had a strong incentive to manipulate the regulatory  
10 structures to prevent generic entry. Even if Defendants listed a fraudulently-obtained patent in the  
11 Orange Book—one that Defendants knew would be invalidated in court or by the Patent Trial and  
12 Appeal Board ("PTAB") at the Patent Office through *Inter Partes* Review ("IPR")—the 30-month  
13 delay caused by forcing generic manufacturers to file Paragraph IV certifications and litigate  
14 infringement actions would allow Defendants to reap over \$2.5 billion in Zytiga sales at unlawful  
15 monopoly prices. A significant portion of these sales would be (and in fact have been) paid for with  
16 government funds through Medicare, Medicaid, and other programs.

## 17 **VI. ALLEGATIONS CONCERNING DEFENDANTS' FALSE CLAIMS**

### 18 **A. Defendants' Patent Exclusivity for Zytiga Should Have Ended in December 2016**

19 56. Zytiga (abiraterone acetate) is indicated in combination with prednisone for the  
20 treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). Abiraterone  
21 acetate works by suppressing synthesis of testosterone. Co-administration with prednisone counters  
22 abiraterone acetate's side-effects, such as increased risk of hypertension.

23 57. Defendants jointly collaborate in the development, manufacture, sale and distribution  
24 of Zytiga.

25 58. By April 2016, Zytiga's FDA-approved exclusivity expired.

26 59. On December 16, 2016, the '213 Patent, which protected the chemical compound for  
27 Zytiga (abiraterone acetate), expired.  
28

**B. Defendants' Fraudulent Prosecution of the '438 Patent**

60. The Patent Office allowed the '438 Patent because of false and misleading statements Defendants made during the patent's examination. The Patent Office originally rejected the '438 Patent application as obvious over the prior art. To overcome that rejection, Defendants made several submissions to the Patent Office to show that Zytiga was a commercial success. But Defendants' submissions to the Patent Office were false, misleading, and misrepresentative of Zytiga's actual commercial success.

61. Patent applicants have a duty of candor and good faith to the Patent Office. For example, under 37 C.F.R. 1.56, "each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section."

62. Under applicable patent law, an application for a patent will be rejected by the Patent Office if the Patent Office uncovers prior art that shows the claimed invention to be obvious. By doing so, the Office establishes a *prima facie* case of obviousness. To overcome a *prima facie* case of obviousness, the patent applicant has a number of options, including: (i) narrowing the invention to distinguish over the prior art; (ii) arguing the prior art does not render the claim obvious; or (iii) submitting objective evidence of secondary considerations.

63. Secondary considerations of non-obviousness can come in many different forms. The most common forms are, *inter alia*: (a) the invention has achieved commercial success resulting from the supposedly patentable subject matter; (b) the invention satisfies a long-felt but unsolved need; (c) or the invention yields unexpected and surprising results. In each case, the patent applicant argues that even if a *prima facie* case of obviousness exists, the patent nevertheless should be allowed based on a secondary consideration of non-obviousness. Evidence of commercial success is significant only if there is a nexus between the claimed invention and the commercial success. If the feature creating the commercial success is not due to the patented invention, then the success is not pertinent. This is well-known by practitioners in the field, particularly Defendants, who have large

1 and well-funded internal legal departments with access to significant and highly-qualified outside  
2 counsel.

3 **C. Defendants Submit Fraudulent and Misleading Evidence to the Patent Office**

4 64. The '438 Patent resulted from a lengthy prosecution before the Patent Office. It began  
5 in February 2011 when Defendants filed patent application number 13/034,340 (the "'340  
6 Application"). The '340 Application eventually resulted in the issuance of the fraudulently obtained  
7 '438 Patent. The proposed invention claimed a method for treating prostate cancer through co-  
8 administration of abiraterone acetate and prednisone (a corticosteroid).

9 65. The Patent Office repeatedly rejected Defendants' '340 Application on the ground  
10 that co-administering abiraterone acetate with prednisone to treat prostate cancer was obvious in light  
11 of the prior art. To overcome this rejection, Defendants submitted fraudulent and misleading  
12 evidence they misrepresented to the Patent Office as demonstrating Zytiga's commercial success  
13 attributable to the claimed invention.

14 66. On February 3, 2012, the Patent Office rejected Defendants' '340 Application on the  
15 ground that the claimed invention was obvious based on prior art.

16 67. On July 3, 2012, J&J, on behalf of Defendants, submitted to the Patent Office  
17 purported evidence of Zytiga's commercial success. Defendants' July 3 submission asserted that  
18 Zytiga enjoyed commercial success because, within the first year of its release, "worldwide sales  
19 were over \$400 million." Defendants, however, did not attempt to demonstrate that the purportedly  
20 high sales amount were related, or had the requisite nexus, to the claimed patentable subject matter  
21 of the '340 Application, as required.

22 68. On or about September 11, 2012, the Patent Office once again rejected Defendants'  
23 submission and affirmed that the claims in the '340 Application were obvious in light of the prior art:  
24 "It would have been obvious to one of ordinary skill in the art at the time the invention was made to  
25 employ both prednisone and abiraterone acetate, in the dosage herein claimed, together in a method  
26 of treating prostate cancer, including refractory prostate cancer."

27 69. The Patent Office also rejected Defendants' claim of commercial success based on  
28



1 the amount of Zytiga sales, because even a high amount of net sales after initial product launch is  
2 insufficient, by itself, establish commercial success or the required nexus with the claimed patentable  
3 subject matter. Thus, the Patent Office determined that Defendants' arguments concerning  
4 "commercial success have been considered, but are not found persuasive." The Patent Office  
5 informed Defendants, to have their application granted, they could not rely solely on gross sales  
6 figures without providing "evidence as to market share."

7 70. In rejecting Defendants' application, the Patent Office said:

8 Furthermore, gross sales figures do not show commercial success absent  
9 evidence as to market share, *Cable Electric Products, Inc. v. Genmark, Inc.*,  
10 770 F.2d 1015, 226 USPQ 881 (Fed. Cir. 1985), or as to the time period  
11 during which the product was sold, or as to what sales would normally be  
12 expected in the market, *Ex parte Standish*, 10 USPQ2d 1454 (Bd. Pat. App.  
& Inter. 1988). In the instant case, there is no evidence of commercial  
success was provided.

13 Defendants therefore were on notice that a showing of commercial success would require  
14 information concerning the successful capture of market share, relevant time period, and what sales  
15 would normally be expected without the claimed invention.

16 71. In particular, the courts and the Patent Office look to evidence of *increasing* market  
17 share and the maintenance of such shares in the face of competitors and other adverse market forces,  
18 unless competitors' market entry was precluded or hindered for reasons other than the merits of the  
19 claimed invention (e.g., because of blocking patents). *See, e.g., Galderma Labs., L.P. v. Tolmar, Inc.*, 737  
20 F.3d 731, 740-41 (Fed. Cir. 2013); *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.*, 776 F.2d 281,  
21 291 (Fed. Cir. 1985). Defendants knew that the only way the Patent Office would approve the '340  
22 Application was to demonstrate that Zytiga's market share increased or were maintained against  
23 competing products as a result of the claimed invention in the '340 Application (*i.e.*, the co-  
24 administration of abiraterone acetate and prednisone).

25 72. In response to the Patent Office's latest rejection of the '340 Application, on June 4,  
26 2013, J&J submitted additional materials on behalf of Defendants that Defendants represented to be  
27 truthful evidence demonstrating Zytiga's commercial success as a result of the invention claimed in  
28

1 the '340 Application. The only additional evidence that Defendants provided that related to a  
2 purported *increase* in Zytiga's market share involved chemo-naïve mCRPC patients. For this sub-  
3 market, Defendants made the following misleading and fraudulent statements, contrary to  
4 Defendants' duty of candor and good faith owed to the Patent Office:

5 [S]hortly after its approval for chemo-naïve patients in December 2012,  
6 ZYTIGA had a market share of 15%. As of April 2013, ZYTIGA's market  
7 share was 20%, higher than two other available therapies, docetaxel and  
8 XTANDI, and approaching the market share of bicalutamide, a drug first  
9 approved in 2001 for prostate cancer.

10 73. Because chemo-naïve patients comprised over 70% of the mCRPC market,  
11 Defendants told the Patent Office that Zytiga's total market share in the mCRPC market increased  
12 approximately 3% from December 2012 to April 2013 (despite Zytiga's market share decline in the  
13 chemo refractory submarket).

14 74. Defendants' representations to the Patent Office concerning Zytiga's share of the  
15 mCRPC market was misleading and fraudulent. They fell well below the level of good-faith and  
16 candor required from patent applicants.

17 a. Defendants' statement was fraudulent and misleading because Xtandi had not  
18 been approved by the FDA for chemo-naïve mCRPC patients between December 2012 and April  
19 2013. In fact, Xtandi would not be approved for chemo-naïve patients until September 2014. Xtandi  
20 is Zytiga's principal competitor in the mCRPC market. Indeed, even though Xtandi was not  
21 approved for the respective chemo refractory and chemo-naïve markets until after Zytiga, Xtandi  
22 overtook Zytiga in market share and number of prescriptions written by the end of 2015. For the  
23 chemo naïve market, Xtandi's market share quickly surpassed Zytiga's market share shortly after  
24 Xtandi's FDA approval in the chemo-naïve submarket. Approximately 16 months after Xtandi's  
25 FDA approval for the chemo-naïve submarket, Xtandi had overtaken Zytiga as the dominant drug for  
26 chemo-naïve mCRPC patients and for mCRPC patients overall.

27 b. Defendants' misrepresentation concerning Zytiga's performance against its  
28 primary rival, Xtandi, was knowing and intentional. In the same submission, Defendants  
29 acknowledged that Zytiga's patient market share in the chemo refractory mCRPC market had

1 plummeted from 70% in July 2012 to 57% by April 2013. Defendants explained the drop in Zytiga's  
2 market share, in part, by the fact that Xtandi had been approved by the FDA for chemo-refractory  
3 mCRPC patients in August 2012, and thus was available to compete with and take market share away  
4 from Zytiga.

5 c. Defendants' reference to Xtandi's FDA approval in August 2012 for the  
6 chemo refractory mCRPC market—the specific market for which Defendants were trying to explain  
7 a drop in Zytiga's market share—demonstrates Defendants' knowledge concerning the importance  
8 of FDA approval for specific indications in which market shares are being compared.

9 d. Moreover, in attempting to demonstrate Zytiga's increasing “market share”  
10 in the chemo-naïve mCRPC market, Defendants reported data from December 2012 through April  
11 2013. In contrast, Defendants reported data for the chemo-refractory market starting in July 2012.  
12 Defendants justified their decision to provide the Patent Office with “market share” data having  
13 different starting time periods (as between the chemo refractory and chemo-naïve markets) by  
14 emphasizing that, whereas Zytiga obtained FDA approval for the chemo refractory market in April  
15 2011, Zytiga did not obtain FDA approval in the chemo-naïve market until December 2012. This  
16 demonstrates that Defendants knew that the date of FDA approval was a material consideration  
17 when assessing the strength of a drug's market share in a relevant market segment. Defendants took  
18 great pains to emphasize the precise dates when Zytiga was approved for the chemo refractory and  
19 chemo-naïve markets, and adjusted their data to fit the relevant starting time periods, because  
20 Defendants knew that accurate FDA-approval dates were important considerations when assessing  
21 the strength of a drug's comparative market share. Nevertheless, Defendants willfully withheld  
22 Xtandi's relevant FDA approval dates to the Patent Office, even though Defendants knew that such  
23 an omission made their submission materially false and misleading, and even though Defendants'  
24 duties of candor and good faith required Defendants to disclose it.

25 e. Defendants' representations to the Patent Office concerning Zytiga's “market  
26 share” are also misleading because, upon information and belief, the “market share” percentage that  
27 Defendants provided to the Patent Office were based on Zytiga's *patient* market share, not its direct  
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1 sales market share compared with other competing drugs. This is misleading and contrary to  
2 Defendants' duty of candor and good faith, because patients suffering from prostate cancer often  
3 take many drugs. Because such a "market share" figure measures the percentage of patients who are  
4 prescribed the drug, and *not* the market share of a drug based on its actual sales compared with sales  
5 of competing products, the total patient market share can substantially *exceed* 100%. In fact, it was  
6 well-known by people skilled in the art—but not disclosed to the Patent Office—that mCRPC  
7 patients typically build a tolerance to one drug, and move to another. Therefore, Defendants' use of  
8 patient share data when representing to the Patent Office that "shortly after its approval for chemo-  
9 naïve patients in December 2012, ZYTIGA had a market share of 15%. As of April 2013, ZYTIGA's  
10 market share was 20%, higher than two other available therapies, docetaxel and XTANDI" was  
11 fraudulent and misleading.

12 f. Defendants' representations to the Patent Office concerning Zytiga's "market  
13 share" in the chemo-naïve mCRPC market is also misleading because Zytiga's supposedly increasing  
14 "market share" was compared with the declining market share of bicalutamide, an older anti-  
15 androgen drug. This was a misleading comparison. Since at least 2010, the medical profession and  
16 those skilled in the relevant arts knew that bicalutamide lowered prostate-specific antigen ("PSA")  
17 levels without materially increasing survivability. Therefore, by 2012, bicalutamide was increasingly  
18 being prescribed in the chemo-naïve mCRPC market only for specific purposes in conjunction with  
19 treatment that was considered to be more efficacious. Particularly in light of Defendants' use of  
20 "patient" share data as a proxy for "market share," Defendants' comparison of Zytiga with  
21 bicalutamide to purportedly demonstrate that Zytiga's market share was increasing against  
22 competitors (such as bicalutamide) by reason of the claimed invention (co-administration of  
23 abiraterone acetate with prednisone) was misleading. Defendants knew the facts that made such  
24 comparison misleading but willfully failed to inform the Patent Office of such facts.

25 75. Relying on Defendants' misrepresentation concerning Zytiga's growth in the chemo-  
26 naïve mCRPC market, the Patent Office issued a Notice of Allowance for the '340 Application,  
27 which led to the issuance of the '438 Patent. The sole reason that the Patent Office gave for allowing  
28



1 the '438 Patent—despite its prior rejections on the ground that the claimed invention was obvious in  
2 light of the prior art—was because of the (misleading) evidence that Defendants submitted  
3 concerning Zytiga's supposed commercial success. As the Patent Office explained in granting  
4 Defendants' application, the "commercial success of the combination of prednisone and abiraterone  
5 to treat prostate cancer obviate the rejection under 35 USC 103(a)."

6 76. The Patent Office had previously rejected Defendants' proffer of commercial success  
7 because the earlier proffer was based on Zytiga's high sales revenue but lacked evidence concerning  
8 Zytiga's market share. The only evidence Defendants provided concerning Zytiga's increasing  
9 market share was the fraudulent and misleading statements relating to Zytiga's growth in the chemo-  
10 naïve mCRPC market. Therefore, the single most reasonable explanation for the Patent Office's  
11 approval of the '438 Patent was Defendants' fraudulent and misleading statements concerning  
12 Zytiga's growth in the chemo-naïve mCRPC market.

13 77. Defendants made other misleading statements in their June 4, 2013 submission to the  
14 Patent Office, contrary to Defendants' duties of candor and good faith.

15 a. Defendants stated that Zytiga was "the most successful oral oncology launch  
16 in history." This was misleading because numerous non-oral cancer drugs have been far more  
17 successful than Zytiga. Defendants knew this but failed to disclose the information to the Patent  
18 Office.

19 b. All drugs for treating CRPC have short efficacy periods because the disease  
20 quickly becomes resistant to a given drug. In practice, this means that patients frequently switch  
21 medications. This suggests that any new CRPC drug is likely to have some immediate commercial  
22 success. Therefore, the immediate commercial success of any new CRPC drug is not necessarily  
23 unexpected or the result of innovation. Indeed, because CRPC drugs have short efficacy periods,  
24 Zytiga's purported commercial success described by Defendants lacked the requisite nexus to the  
25 claimed invention in the '340 Application. Defendants knew these facts at the time they made their  
26 representations to the Patent Office. Nevertheless, Defendants failed to disclose them to the Patent  
27 Office, even though Defendants' duties of candor and good faith required such disclosure.  
28

1           c.     Zytiga earned high revenue for Defendants because it does not sequence well  
2 with its biggest competitor in the chemo refractory mCRPC market, Xtandi. This means Zytiga had a  
3 natural commercial advantage over Xtandi simply because Zytiga was approved and launched first.  
4 For this reason, Zytiga's purported commercial success described by Defendants lacked the requisite  
5 nexus to the claimed invention in the '340 Application. These facts were known by Defendants at the  
6 time they made their representations to the Patent Office. Nevertheless, Defendants failed to  
7 disclose them to the Patent Office, even though Defendants' duties of candor and good faith required  
8 such disclosure.

9           d.     New urology guidelines for treatment of CRPC patients in 2013 indicated  
10 many factors that should guide a doctor's decision to prescribe one drug instead of another. Zytiga  
11 was recommended in some cases because it was the least toxic. This recommendation was a  
12 significant factor explaining the high sales revenue for Zytiga, and it had nothing to do with the  
13 claimed innovation embodied in the '438 Patent (*i.e.*, the administration of abiraterone with  
14 prednisone). Defendants knew these facts at the time they made their representations to the Patent  
15 Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though  
16 Defendants' duties of candor and good faith required such disclosure.

17           e.     The '213 Patent was a blocking patent that precluded generic entry or even  
18 meaningful research in abiraterone acetate by competing drug manufacturers prior to December  
19 2016. Abiraterone acetate was one of the first of several new drugs for the mCRPC market that were  
20 approved and introduced beginning in or around 2010. Abiraterone acetate was the first major new  
21 drug that could be orally administered. Therefore, the '213 Patent casts substantial doubt that  
22 Zytiga's high sales revenues after launch resulted from the claimed innovation in the '438 Patent.  
23 This is a material fact that was known by Defendants and should have been disclosed to the Patent Office,  
24 particularly since the Patent Office and the courts have repeatedly stressed the importance of a blocking  
25 patent when determining whether a drug's commercial success obviates a finding of obviousness. *See, e.g.,*  
26 *Merck & Co. v. Teva Pharm. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) ("Because market entry  
27 by others was precluded [due to patent protection and statutory exclusivity], the inference of non-  
28

1 obviousness . . . from evidence of commercial success . . . is weak”); *Galderma Labs., L.P. v. Tolmar,*  
2 *Inc.*, 737 F.3d 731, 740-41 (Fed. Cir. 2013) (same). Moreover, the ’438 Patent is not a continuation of  
3 the ’213 Patent, and thus the Examiners that considered each of the patent applications were not the  
4 same person. The Examiner for the ’438 Patent was San-Ming Hui, whereas the Examiner for the  
5 ’213 Patent was Anthony Bottino. The Examiner for the ’438 Patent cannot therefore be presumed  
6 to have been aware of the earlier blocking ’213 Patent. Defendants failed to disclose the existence of  
7 the ’213 Patent as a blocking patent to the Patent Office when pursuing the ’438 Patent, even though  
8 Defendants’ duties of candor and good faith required such disclosure.

9 f. The ’438 Patent claims the combination of abiraterone acetate and prednisone  
10 for the purpose of alleviating certain side-effects of abiraterone acetate, such as increased  
11 hypertension. However, drugs for mCRPC usually extend a patient’s life by a few months, at best.  
12 Thus, alleviating side effects may not have actually been a factor in the decision to prescribe or take  
13 Zytiga as of 2013, when Defendants made their representations to the Patent Office. Accordingly,  
14 Defendants’ statements regarding the commercial success of Zytiga misled the Patent Office about  
15 the required “nexus” between the commercial success of the drug and the patent, which is a  
16 requirement of showing commercial success as a secondary consideration under patent law.  
17 Defendants knew these facts at the time they made their representations to the Patent Office.  
18 Nevertheless, Defendants failed to disclose them to the Patent Office, even though Defendants’  
19 duties of candor and good faith required such disclosure.

20 g. Defendants stated to the Patent Office that, “Zytiga had almost 70% market  
21 share in July of 2012 for chemo refractory prostate cancer patients, just slightly over a year after  
22 ZYTIGA’s initial approval, and despite the fact that a [*sic*] JEV TANA had been approved two years  
23 earlier.” However, Zytiga is an oral medication, whereas Jevtana is a one-hour intravenous infusion.  
24 That distinction alone had an impact on Zytiga’s purported success compared to Jevtana. Yet,  
25 Defendants did not disclose to the Patent Office that Zytiga’s commercial success compared to  
26 Jevtana related to different routes of administration. Importantly, neither the pending claims in the  
27 ’340 Application nor the issued claims in the ’438 Patent are limited to oral administration. On the  
28



1 contrary, the '438 Patent discloses embodiments for the claimed methods that can be administered  
2 intravenously. Thus, Defendants misleadingly withheld information showing that the required  
3 "nexus" between the patented claims and the purported commercial success did not exist. These  
4 facts were known by Defendants at the time Defendants made their representations to the Patent  
5 Office. Nevertheless, Defendants failed to disclose them to the Patent Office, even though  
6 Defendants' duties of candor and good faith required such disclosure.

7 h. Defendants did not disclose to the Patent Office that, in 2013, the price of  
8 Zytiga was considerably less than Xtandi and Jevtana. Xtandi cost approximately 35% more per year,  
9 and Jevtana cost approximately 50% more. These facts were known by Defendants at the time  
10 Defendants made their representations to the Patent Office. Nevertheless, Defendants failed to  
11 disclose them to the Patent Office, even though Defendants' duties of candor and good faith required  
12 such disclosure.

13 i. Zytiga is not always administered or prescribed with prednisone. The sales of  
14 Zytiga that are not co-administered with prednisone necessarily lack the required nexus to the '438  
15 Patent, since the '438 Patent requires co-administration with prednisone to be infringed. Upon  
16 information and believe, abiraterone is prescribed and sold without prednisone at least 10% of the  
17 time. For these sales, there is no nexus to the '438 Patent. On information and belief, during  
18 prosecution of the '340 Application, Defendants were aware that at least 10% of Zytiga sales were  
19 prescribed or administered without the patented co-administration with prednisone. Thus, by failing  
20 to account for these sales that necessarily lacked a nexus to the '438 Patent, Defendants misleadingly  
21 inflated Zytiga's market share in the course of describing the purported commercial success of the  
22 alleged invention in the '438 Patent. These facts were known by Defendants at the time Defendants  
23 made their representations to the Patent Office. Nevertheless, Defendants failed to disclose them to  
24 the Patent Office, even though Defendants' duties of candor and good faith required such disclosure  
25 .

26 78. In making each of these fraudulent or misleading statements to the Patent Office,  
27 Defendants knew that the evidence supposedly demonstrating Zytiga's commercial success was  
28



1 highly material to the issue of patentability of the claims in the '438 Patent.

2 79. Based on Defendants' false and misleading representations and reliance thereon, the  
3 Patent Office allowed the claims in the '340 Application and issued the '438 Patent.

4 **D. Defendants Used the Fraudulently Obtained '438 Patent to Block Generic Competition**

5 80. After fraudulently obtaining the '438 Patent, Defendants listed the patent in the  
6 Orange Book along with the '213 Patent. During all relevant times, Defendants listed in the Orange Book  
7 only two patents covering Zytiga: the '213 Patent, and the '438 Patent.

8 81. The '213 Patent (which is directed to the compound, abiraterone acetate) expired on  
9 December 13, 2016, and the '438 Patent will expire in approximately 2027. Thus, after December 13,  
10 2016, only the '438 Patent blocked generic competition for abiraterone acetate.

11 82. Prior to December 2016, numerous generic companies filed ANDAs with the FDA  
12 seeking approval to distribute a generic version of Zytiga. These companies include Actavis  
13 Laboratories, FL, Inc.; Amneal Pharmaceuticals, LLC and Amneal Pharmaceuticals of New York,  
14 LLC; Apotex Inc. and Apotex Corp.; Amerigen Pharmaceuticals Limited; Citron Pharma LLC; Dr.  
15 Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.; Glenmark Pharmaceuticals Inc. and  
16 affiliated entities.; Hetero USA Inc. and affiliated entities; Mylan Pharmaceuticals Inc. and Mylan  
17 Inc.; Par Pharmaceuticals, Inc. and Par Pharmaceutical Companies, Inc; Sun Pharmaceutical  
18 Industries Ltd. and Sun Pharmaceuticals Industries, Inc.; Teva Pharmaceuticals USA, Inc.;  
19 Wockhardt Bio A.G.; Wockhardt USA LLC and Wockhardt Ltd.; West-Ward Pharmaceutical Corp.;  
20 and Hikma Pharmaceuticals, LLC (collectively, the "ANDA Filers").

21 83. The vast majority of the ANDA Filers filed their ANDAs in June and July 2015.

22 84. Given the unusual breadth of ANDA filings for Zytiga, over a dozen generic  
23 manufacturers would have been able to file Paragraph I, II, or III certifications and gain approval to  
24 introduce generic alternatives to Zytiga by December 2016, but for Defendants' wrongful listing of the  
25 fraudulently obtained '438 Patent in the Orange Book.

26 85. Defendants' listing of the '438 Patent in the Orange Book constituted a false and  
27 fraudulent statement to the U.S. government.  
28

1           86. Because Defendants fraudulently obtained the '438 Patent and improperly listed it in  
2 the Orange Book, Defendants forced the ANDA Filers to file Paragraph IV certifications.

3           87. Defendants instituted objectively baseless litigation against the ANDA Filers, alleging  
4 infringement of Defendants' invalid, unenforceable, and fraudulently-obtained '438 Patent. By filing  
5 the infringement lawsuits, Defendants triggered the 30-month stays on FDA approval of the ANDA  
6 Filers' applications to market generic alternatives to Zytiga. Defendants commenced these sham  
7 litigations for the anticompetitive and unlawful purpose of delaying or preventing generic entry into  
8 the relevant market. The 30-month stay will expire for the majority of ANDA Filers in or about January  
9 2018. Accordingly, Defendants have unlawfully but successfully blocked generics from entering the  
10 market since at least December 2016.

11           88. Because Defendants' fraudulent scheme alleged herein, tentative approval for the  
12 ANDA Filers have been wrongfully delayed. For example, tentative approval for the Wockhardt  
13 ANDA Filers was not granted by the FDA until October 18, 2017. The FDA granted tentative  
14 approval for the Amneal entities on October 27, 2017.

15           89. Because of Defendants' false and misleading statements to the Patent Office in  
16 procuring the '438 Patent, consumers have been deprived of, and continue to be deprived of, a lower-  
17 cost generic form of Zytiga from at least December 13, 2016.

18 **E. Defendants' Fraudulent Scheme Has Resulted in Thousands of False Claims**

19           90. Defendants initiated the fraudulent scheme alleged herein to allow them to continue  
20 selling Zytiga at monopolist prices after the expiration of the '213 Patent. Defendants knew and  
21 intended to unlawfully sell Zytiga at monopolist prices during the 30-month stay and pending the  
22 Hatch-Waxman litigations resulting from Defendants' improper listing of the '438 Patent in the  
23 Orange Book.

24           91. Defendants' fraudulent scheme erected significant barriers to the introduction of  
25 generic alternatives to Zytiga in interstate commerce and constitutes a willful attempt to retain  
26 monopoly power over the relevant market. Defendants' wrongful conduct has restrained  
27  
28

1 competition in violation of federal and state antitrust laws, enabling Defendants to charge the United  
2 States Government and the Plaintiff States illegally-inflated prices for abiraterone acetate.

3 92. Defendants have used their illegal monopoly to overcharge the United States  
4 Government and the Plaintiff States for abiraterone acetate.

5 93. Defendants knew that the United States and the Plaintiff States would be purchasers  
6 and third-party payers for Zytiga through direct or indirect sales of Zytiga or the payment of claims  
7 for prescription drug reimbursement submitted by providers under government programs, including  
8 Medicare and Medicaid.

9 94. Defendants knew that they would be submitting claims to the United States and the  
10 Plaintiff States and causing or inducing others to submit claims based on Defendants' illegally-  
11 inflated pricing for Zytiga. Defendants were also well-aware of the statutory structures that govern  
12 the methods by which the United States and the Plaintiff States reimbursed outpatient drugs covered  
13 under Medicare and Medicaid.

14 95. Defendants knew that, if generic alternatives to Zytiga were available, that at  
15 approximately 90% of prescriptions for Zytiga would have been substituted for a generic version.

16 96. Defendants, their employees and agents, individually and in concert, knowingly  
17 submitted or caused to be submitted false claims to the United States Government and the Plaintiff  
18 States to secure payments for illegally-inflated prices for abiraterone acetate since at least December  
19 13, 2016.

20 97. The United States Government and the Plaintiff States were unaware of Defendants'  
21 fraudulent scheme, misrepresentations to the Patent Office, and wrongful listing of the '438 Patent  
22 in the Orange Book at the time they paid False Claims.

23 98. Defendants' misrepresentations and fraudulent course of conduct were material to  
24 the United States Government and the Plaintiff States paying the False Claims. In purchasing drugs  
25 or reimbursing for prescriptions as an end-payor, the United States Government and the Plaintiff  
26 States require that the prices they pay or the amounts they reimburse have not been manipulated,  
27 inflated, or maintained through the wrongful suppression of competition or other wrongful conduct.  
28



1 a. Because Zytiga did not have any FDA-approved competitors—and therefore there  
2 was no “adequate price competition”—Defendants were required to provide the Government full  
3 and accurate cost or pricing data as a condition to receiving payment.

4 b. Defendants’ disclosure was required because the Government may pay only a “fair  
5 and reasonable” price for pharmaceuticals.

6 c. As part of its required disclosure, Defendants were obligated to include all facts that a  
7 prudent buyer or seller would reasonably expect to affect prices—such as whether the prices have  
8 been inflated through anticompetitive conduct.

9 d. Upon information and belief, Defendants certified that the cost or pricing data it  
10 provided to the Government was “accurate, complete and current.” Contrary to their certification,  
11 however, Defendants failed to disclose to the Government that the prices they were charging for  
12 Zytiga were monopolist prices based on Defendants’ fraudulent exclusion of generic competition.  
13 Because the Government may pay only a “fair and reasonable price” for pharmaceuticals based on  
14 “accurate, complete and current” cost or pricing data, Defendants’ misrepresentations and  
15 fraudulent conduct were material to the Government’s payments of the False Claims alleged herein.  
16 Had the Government or the Plaintiff States known about Defendants’ misrepresentations and  
17 fraudulent scheme to obtain the ’438 Patent to block generic competition for abiraterone acetate, the  
18 Government and the Plaintiff States would not have paid or reimbursed for Zytiga at Defendants’  
19 monopolist prices.

20 e. Reimbursements under Medicare and Medicaid regulations assume that a drug’s  
21 price has not been wrongfully inflated or maintained through anticompetitive conduct or the  
22 wrongful exclusion of competitors. The Centers for Medicare & Medicaid Services (“CMS”), which  
23 is part of the DHHS and administers various programs including Medicare and Medicaid. CMS  
24 requires drug manufacturers (such as Defendants) to provide it with accurate manufacturer prices  
25 for compilation in CMS’s Average Manufacturer Price (“AMP”) and Average Selling Price  
26 (“ASP”) database files. CMS uses their AMP and ASP calculations to set certain price limits and  
27 reimbursement levels for pharmaceutical products under the Medicare and Medicaid programs. An  
28

1 integral assumption in CMS's reimbursement decisions is that pharmaceutical prices reflect  
2 competitive market prices that have not been unlawfully inflated or maintained through  
3 anticompetitive conduct or the wrongful exclusion of competitors. Therefore, Defendants'  
4 misleading statements and fraudulent conduct are necessarily material to the Government's  
5 payments of the False Claims alleged herein.

6 f. For example, CMS calculates Medicare reimbursement rates for certain outpatient  
7 drugs based on a percentage ASP. For drugs with therapeutic equivalents, CMS is required to weigh  
8 the calculation of ASPs based on drug utilization (or volume of sales). Because of the number of  
9 generic competitors that would have entered the market in December 2016, generic versions of  
10 abiraterone acetate would have quickly captured at least 90% of the market. Therefore, CMS's ASP  
11 calculations would have been heavily weighted towards the average lower generic selling prices.

12 g. As another example, CMS calculates every month a "Federal Upper Limit" for  
13 Medicaid reimbursements of covered pharmaceuticals based on a percentage of the AMP. The AMP  
14 calculation must include the prices of pharmaceutically and therapeutically equivalent generic  
15 alternatives and be weighted towards those drugs with the highest utilization or *volume* of sales.  
16 Because of the number of generic competitors that would have entered the market in December  
17 2016, generic versions of abiraterone acetate would have quickly captured at least 90% of the market,  
18 and the Federal Upper Limit for Zytiga prescriptions would have been heavily weighted towards the  
19 average lower generic selling prices. Therefore, Defendants' misrepresentations and fraudulent  
20 conduct were *necessarily* material to the Government's and Plaintiff States' payments of the False  
21 Claims, because they would have been statutory *prohibited* from paying the higher amount requested  
22 in the False Claims.

23 99. Defendants' misrepresentations and fraudulent conduct allowed Defendants to bill  
24 (or cause the submission to and payment of reimbursement claims by) the United States  
25 Government and the Plaintiff States for a high-priced or defectively-priced good (*i.e.*, a patented drug  
26 with no generic competitors) than what was actually provided (a non-patented drug that should have  
27 had numerous generic competitors). On information and belief, the United States Government and  
28



1 the Plaintiff States paid or reimbursed for Zytiga at Defendants' unlawfully inflated monopolist  
 2 prices, but they would not have entered into such contracts or paid such amounts had they known  
 3 the true facts at the time of contracting or payment. The United States Government and the Plaintiff  
 4 States would not have accepted or made payments on invoices for patented Zytiga but for the  
 5 fraudulently-obtained '438 Patent.

6 100. But for Defendants' misrepresentations and fraudulent conduct, approximately 90%  
 7 or more of the False Claims to the United States Government and the Plaintiff States for Zytiga  
 8 would have instead been for significantly lower-priced generic abiraterone acetate, and not Zytiga.

9 101. Using its fraudulently-obtained patent rights, Defendants have submitted or caused to  
 10 be submitted thousands of False Claims to the United States Government and the Plaintiff States,  
 11 either through sales of Zytiga to government purchasers or False Claims for reimbursement for  
 12 Zytiga submitted to the Medicare and Medicaid programs. Defendants submitted the False Claims or  
 13 caused the False Claims to be submitted to the United States Government and the Plaintiff States  
 14 based on unlawful pricing above the what the fair market value of abiraterone acetate would have  
 15 been but for Defendants' unlawful and fraudulent blocking of generic entry.

16 102. Defendants submitted or caused submission of False Claims with false certifications  
 17 of compliance with law. The United States Government and the Plaintiff States conditioned payment  
 18 or reimbursement for Zytiga upon these false certifications. Unaware of Defendants' fraudulent  
 19 scheme, the United States Government and the Plaintiff States issued payment on those False  
 20 Claims.

21 **Count I**  
 22 **False Claims Act**  
**31 U.S.C. §§ 3729–3733**

23 103. Relator realleges and incorporates by reference all foregoing allegations as though  
 24 fully set forth herein.

25 104. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C.  
 26 §§ 3729–3733, as amended.  
 27  
 28

105. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims for payment of Zytiga.

106. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the United States. Relator has no control over, or dealings with, such entities, and has no access to the records in their possession.

107. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the Government would not have paid but for Defendants' illegal conduct.

108. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

109. Additionally, the United States is entitled to a maximum penalty of up to \$21,916 for each and every violation alleged herein.

**Count II**  
**California False Claims Act**  
**Cal. Gov't Code §§ 12650-12656**

110. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

111. This is a claim for treble damages and penalties under the California False Claims Act.

112. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

113. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

114. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

1 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
2 Zytiga.

3 115. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
4 were not entitled to be paid by the State of California—through any state funded program, including,  
5 without limitation, Medicaid—for Zytiga.

6 116. Through the acts described herein, Defendants knowingly presented, or caused to be  
7 presented, false or fraudulent claims to the State of California.

8 117. Relator cannot at this time identify all of the false claims for payment that were caused  
9 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
10 State of California. Relator has no control over or dealings with such entities and has no access to the  
11 records in their possession.

12 118. The State of California, unaware of the falsity of the records, statements and claims  
13 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
14 California would not have paid but for Defendants' illegal conduct.

15 119. By reason of Defendants' acts, the State of California has been damaged, and  
16 continues to be damaged, in substantial amount to be determined at trial.

17 120. Additionally, the State of California is entitled to a statutory penalty for each and  
18 every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

19 121. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
20 State of California pursuant to Cal. Gov't Code § 12652(c)(1).

21 **Count III**  
22 **Colorado Medicaid False Claims Act**  
**Colo. Rev. Stat. §§ 25.5-4-303.5 to -310**

23 122. Relator realleges and incorporates by reference all foregoing allegations as though  
24 fully set forth herein.

25 123. This is a claim for treble damages and penalties under the Colorado Medicaid False  
26 Claims Act.

1           124. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 presented, or caused to be presented, false or fraudulent claims for payment and approval for  
3 prescriptions for Zytiga.

4           125. Through the acts described above, Defendants knowingly, intentionally, and willfully  
5 made or used a false record or statement material to a false or fraudulent claim for payment and  
6 approval for prescriptions for Zytiga.

7           126. Through the acts described above, Defendants conspired to (a) present, or cause to be  
8 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
9 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
10 Zytiga.

11           127. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
12 were not entitled to be paid by the State of Colorado—through any state funded program, including,  
13 without limitation, Medicaid—for Zytiga.

14           128. Through the acts described herein, Defendants knowingly presented, or caused to be  
15 presented, false or fraudulent claims to the State of Colorado.

16           129. Relator cannot at this time identify all of the false claims for payment that were caused  
17 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
18 State of Colorado. Relator has no control over or dealings with such entities and has no access to the  
19 records in their possession.

20           130. The State of Colorado, unaware of the falsity of the records, statements and claims  
21 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
22 Connecticut would not have paid but for Defendants' illegal conduct.

23           131. By reason of Defendants' acts, the State of Colorado has been damaged, and  
24 continues to be damaged, in substantial amount to be determined at trial.

25           132. Additionally, the State of Colorado is entitled to a statutory penalty for each and every  
26 violation alleged herein to be determined by the Court in accordance with the relevant statutes.



**Count IV**  
**Connecticut False Claims Act**  
**Conn. Gen. Stat. §§ 4-274 to -289**

135. This is a claim for treble damages and penalties under the Connecticut False Claims Act.

137. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

138. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

139. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Connecticut—through any state funded program, including, without limitation, Medicaid—for Zytiga.

140. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Connecticut.

141. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Connecticut. Relator has no control over or dealings with such entities and has no access to the records in their possession.





151. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Delaware.

152. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Delaware. Relator has no control over or dealings with such entities and has no access to the records in their possession.

153. The State of Delaware, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Delaware would not have paid but for Defendants' illegal conduct.

154. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

155. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Delaware pursuant to Del. Code Ann. tit. 6, § 1203(b).

**Count VI**  
**Florida False Claims Act**  
**Fla. Stat. §§ 68.081-.09**

156. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

157. This is a claim for treble damages and penalties under the Florida False Claims Act.

158. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

159. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

160. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or

1 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
2 Zytiga.

3 161. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
4 were not entitled to be paid by the State of Florida—through any state funded program, including,  
5 without limitation, Medicaid—for Zytiga.

6 162. Through the acts described herein, Defendants knowingly presented, or caused to be  
7 presented, false or fraudulent claims to the State of Florida.

8 163. Relator cannot at this time identify all of the false claims for payment that were caused  
9 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
10 State of Florida. Relator has no control over or dealings with such entities and has no access to the  
11 records in their possession.

12 164. The State of Florida, unaware of the falsity of the records, statements and claims  
13 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
14 Florida would not have paid but for Defendants' illegal conduct.

15 165. By reason of Defendants' acts, the State of Florida has been damaged, and continues  
16 to be damaged, in substantial amount to be determined at trial.

17 166. Additionally, the State of Florida is entitled to a statutory penalty for each and every  
18 violation alleged herein to be determined by the Court in accordance with the relevant statutes.

19 167. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
20 State of Florida pursuant to Fla. Stat. § 68.083.

21 **Count VII**  
22 **Georgia False Medicaid Claims Act**  
**Ga. Code Ann. §§ 49-4-168 to -168.6**

23 168. Relator realleges and incorporates by reference all foregoing allegations as though  
24 fully set forth herein.

25 169. This is a claim for treble damages and penalties under the Georgia False Medicaid  
26 Claims Act.

170. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

171. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

172. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

173. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Georgia—through any state funded program, including, without limitation, Medicaid—for Zytiga.

174. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Georgia.

175. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Georgia. Relator has no control over or dealings with such entities and has no access to the records in their possession.

176. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Georgia would not have paid but for Defendants' illegal conduct.

177. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

178. Additionally, the State of Georgia is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.



179. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Georgia pursuant to Ga. Code Ann. §49-4-168.

**Count VIII**  
**Hawaii False Claims Act**  
**Haw. Rev. Stat. §§ 661-21 to -31**

180. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

181. This is a claim for treble damages and penalties under Hawaii False Claims Act.

182. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

183. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

184. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

185. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Hawaii—through any state funded program, including, without limitation, Medicaid—for Zytiga.

186. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Hawaii.

187. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Hawaii. Relator has no control over or dealings with such entities and has no access to the records in their possession.



188. The State of Georgia, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Hawaii would not have paid but for Defendants' illegal conduct.

189. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

190. Additionally, the State of Hawaii is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

191. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Hawaii pursuant to Haw. Rev. Stat. § 661-25.

**Count IX**  
**Illinois False Claims Act**  
**740 Ill. Comp. Stat. 175/1-175/8**

192. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

193. This is a claim for treble damages and penalties under the Illinois False Claims Act.

194. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

195. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

196. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

197. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Illinois—through any state funded program, including, without limitation, Medicaid—for Zytiga.

198. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Illinois.

199. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Illinois. Relator has no control over or dealings with such entities and has no access to the records in their possession.

200. The State of Illinois, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Illinois would not have paid but for Defendants' illegal conduct.

201. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

202. Additionally, the State of Illinois is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

203. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Illinois pursuant to 740 Ill. Comp. Stat. 175/4(b).

**Count X**  
**Indiana False Claims and Whistleblower Protection Act**  
**Ind. Code §§ 5-11-5.5-1 to -18**

204. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

205. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

206. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

207. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

209. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Indiana—through any state funded program, including, without limitation, Medicaid—for Zytiga.

211. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Indiana. Relator has no control over or dealings with such entities and has no access to the records in their possession.

213. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

215. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Indiana pursuant to Ind. Code § 5-11-5.5-4.

216. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

1           218. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 presented, or caused to be presented, false or fraudulent claims for payment and approval for  
3 prescriptions for Zytiga.

4           219. Through the acts described above, Defendants knowingly, intentionally, and willfully  
5 made or used a false record or statement material to a false or fraudulent claim for payment and  
6 approval for prescriptions for Zytiga.

7           220. Through the acts described above, Defendants conspired to (a) present, or cause to be  
8 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
9 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
10 Zytiga.

11           221. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
12 were not entitled to be paid by the State of Iowa—through any state funded program, including,  
13 without limitation, Medicaid—for Zytiga.

14           222. Through the acts described herein, Defendants knowingly presented, or caused to be  
15 presented, false or fraudulent claims to the State of Iowa.

16           223. Relator cannot at this time identify all of the false claims for payment that were caused  
17 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
18 State of Iowa. Relator has no control over or dealings with such entities and has no access to the  
19 records in their possession.

20           224. The State of Iowa, unaware of the falsity of the records, statements and claims made  
21 or caused to be made by Defendants, paid and continues to pay the claims that the State of Iowa  
22 would not have paid but for Defendants' illegal conduct.

23           225. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to  
24 be damaged, in substantial amount to be determined at trial.

25           226. Additionally, the State of Iowa is entitled to a statutory penalty for each and every  
26 violation alleged herein to be determined by the Court in accordance with the relevant statutes.









1           255. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 made or used a false record or statement material to a false or fraudulent claim for payment and  
3 approval for prescriptions for Zytiga.

4           256. Through the acts described above, Defendants conspired to (a) present, or cause to be  
5 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
6 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
7 Zytiga.

8           257. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
9 were not entitled to be paid by the Commonwealth of Massachusetts—through any state funded  
10 program, including, without limitation, Medicaid—for Zytiga.

11           258. Through the acts described herein, Defendants knowingly presented, or caused to be  
12 presented, false or fraudulent claims to the Commonwealth of Massachusetts.

13           259. Relator cannot at this time identify all of the false claims for payment that were caused  
14 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
15 Commonwealth of Massachusetts. Relator has no control over or dealings with such entities and has  
16 no access to the records in their possession.

17           260. The Commonwealth of Massachusetts, unaware of the falsity of the records,  
18 statements and claims made or caused to be made by Defendants, paid and continues to pay the  
19 claims that the Commonwealth of Massachusetts would not have paid but for Defendants' illegal  
20 conduct.

21           261. By reason of Defendants' acts, the Commonwealth of Massachusetts has been  
22 damaged, and continues to be damaged, in substantial amount to be determined at trial.

23           262. Additionally, the Commonwealth of Massachusetts is entitled to a statutory penalty  
24 for each and every violation alleged herein to be determined by the Court in accordance with the  
25 relevant statutes.

26           263. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
27 Commonwealth of Massachusetts pursuant to Mass. Gen. Laws. ch. 12, § 5C(2).  
28



**Count XV**  
**Michigan Medicaid False Claims Act**  
**Mich. Comp. Laws §§ 400.601-.615**

264. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

265. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

266. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

267. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

268. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

269. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Michigan—through any state funded program, including, without limitation, Medicaid—for Zytiga.

270. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Michigan.

271. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Michigan. Relator has no control over or dealings with such entities and has no access to the records in their possession.

273. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

274. Additionally, the State of Michigan is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

275. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Michigan pursuant to Mich. Comp. Laws § 400.610a.

**Count XVI**  
**Minnesota False Claims Act**  
**Minn. Stat. §§ 15C.01-.16**

**Count XVI**  
**Minnesota False Claims Act**  
**Minn. Stat. §§ 15C.01-.16**

276. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

277. This is a claim for treble damages and penalties under the Minnesota False Claims Act.

278. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

279. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

280. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.



1           291. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 made or used a false record or statement material to a false or fraudulent claim for payment and  
3 approval for prescriptions for Zytiga.

4           292. Through the acts described above, Defendants conspired to (a) present, or cause to be  
5 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
6 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
7 Zytiga.

8           293. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
9 were not entitled to be paid by the State of Montana—through any state funded program, including,  
10 without limitation, Medicaid—for Zytiga.

11           294. Through the acts described herein, Defendants knowingly presented, or caused to be  
12 presented, false or fraudulent claims to the State of Montana.

13           295. Relator cannot at this time identify all of the false claims for payment that were caused  
14 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
15 State of Montana. Relator has no control over or dealings with such entities and has no access to the  
16 records in their possession.

17           296. The State of Montana, unaware of the falsity of the records, statements and claims  
18 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
19 Montana would not have paid but for Defendants' illegal conduct.

20           297. By reason of Defendants' acts, the State of Montana has been damaged, and  
21 continues to be damaged, in substantial amount to be determined at trial.

22           298. Additionally, the State of Montana is entitled to a statutory penalty for each and every  
23 violation alleged herein to be determined by the Court in accordance with the relevant statutes.

24           299. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
25 State of Montana pursuant to Mont. Code Ann. § 17-8-406.  
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27  
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**Count XVIII**  
**Nevada Submission of False Claims to State or Local Government**  
**Nev. Rev. Stat. §§ 357.010-.250**

300. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

301. This is a claim for treble damages and penalties under the Nevada statute relating to the Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010-.250

302. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

303. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

304. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

305. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Nevada—through any state funded program, including, without limitation, Medicaid—for Zytiga.

306. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Nevada.

307. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Nevada. Relator has no control over or dealings with such entities and has no access to the records in their possession.





1           326. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 presented, or caused to be presented, false or fraudulent claims for payment and approval for  
3 prescriptions for Zytiga.

4           327. Through the acts described above, Defendants knowingly, intentionally, and willfully  
5 made or used a false record or statement material to a false or fraudulent claim for payment and  
6 approval for prescriptions for Zytiga.

7           328. Through the acts described above, Defendants conspired to (a) present, or cause to be  
8 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
9 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
10 Zytiga.

11           329. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
12 were not entitled to be paid by the State of New Jersey—through any state funded program,  
13 including, without limitation, Medicaid—for Zytiga.

14           330. Through the acts described herein, Defendants knowingly presented, or caused to be  
15 presented, false or fraudulent claims to the State of New Jersey.

16           331. Relator cannot at this time identify all of the false claims for payment that were caused  
17 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
18 State of New Jersey. Relator has no control over or dealings with such entities and has no access to  
19 the records in their possession.

20           332. The State of New Jersey, unaware of the falsity of the records, statements and claims  
21 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
22 New Jersey would not have paid but for Defendants' illegal conduct.

23           333. By reason of Defendants' acts, the State of New Jersey has been damaged, and  
24 continues to be damaged, in substantial amount to be determined at trial.

25           334. Additionally, the State of New Jersey is entitled to a statutory penalty for each and  
26 every violation alleged herein to be determined by the Court in accordance with the relevant statutes.



1           335. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
2 State of New Jersey pursuant to N.J. Stat. Ann. § 2A:32C-5.

3                                   **Count XXI**  
4                                   **New Mexico Medicaid False Claims**  
5                                   **N.M. Stat. Ann. §§ 27-14-1 to -15**

6           336. Relator realleges and incorporates by reference all foregoing allegations as though  
7 fully set forth herein.

8           337. This is a claim for treble damages and penalties under the New Mexico Medicaid  
9 False Claims Act.

10          338. Through the acts described above, Defendants knowingly, intentionally, and willfully  
11 presented, or caused to be presented, false or fraudulent claims for payment and approval for  
12 prescriptions for Zytiga.

13          339. Through the acts described above, Defendants knowingly, intentionally, and willfully  
14 made or used a false record or statement material to a false or fraudulent claim for payment and  
15 approval for prescriptions for Zytiga.

16          340. Through the acts described above, Defendants conspired to (a) present, or cause to be  
17 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
18 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
19 Zytiga.

20          341. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
21 were not entitled to be paid by the State of New Mexico—through any state funded program,  
22 including, without limitation, Medicaid—for Zytiga.

23          342. Through the acts described herein, Defendants knowingly presented, or caused to be  
24 presented, false or fraudulent claims to the State of New Mexico.

25          343. Relator cannot at this time identify all of the false claims for payment that were caused  
26 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
27 State of New Mexico. Relator has no control over or dealings with such entities and has no access to  
28 the records in their possession.



1           354. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 presented, or caused to be presented, false or fraudulent claims for payment and approval for  
3 prescriptions for Zytiga.

4           355. Through the acts described above, Defendants knowingly, intentionally, and willfully  
5 made or used a false record or statement material to a false or fraudulent claim for payment and  
6 approval for prescriptions for Zytiga.

7           356. Through the acts described above, Defendants conspired to (a) present, or cause to be  
8 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
9 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
10 Zytiga.

11           357. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
12 were not entitled to be paid by the State of New York—through any state funded program, including,  
13 without limitation, Medicaid—for Zytiga.

14           358. Through the acts described herein, Defendants knowingly presented, or caused to be  
15 presented, false or fraudulent claims to the State of New York.

16           359. Relator cannot at this time identify all of the false claims for payment that were caused  
17 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
18 State of New York. Relator has no control over or dealings with such entities and has no access to the  
19 records in their possession.

20           360. The State of New York, unaware of the falsity of the records, statements and claims  
21 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
22 New York would not have paid but for Defendants' illegal conduct.

23           361. By reason of Defendants' acts, the State of New York has been damaged, and  
24 continues to be damaged, in substantial amount to be determined at trial.

25           362. Additionally, the State of New York is entitled to a statutory penalty for each and  
26 every violation alleged herein to be determined by the Court in accordance with the relevant statutes.







382. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Oklahoma.

383. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Oklahoma. Relator has no control over or dealings with such entities and has no access to the records in their possession.

384. The State of Oklahoma, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Oklahoma would not have paid but for Defendants' illegal conduct.

385. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

386. Additionally, the State of Oklahoma is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

387. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Oklahoma pursuant to Okla. Stat. tit. 63, § 5053.3.

**Count XXVI**  
**Rhode Island False Claims Act**  
**R.I. Gen. Laws §§ 9-1.1-1 to -9**

**Count XXVI**  
**Rhode Island False Claims Act**  
**R.I. Gen. Laws §§ 9-1.1-1 to -9**

388. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

389. This is a claim for treble damages and penalties under the Rhode Island False Claims Act.

390. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

1           391. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 made or used a false record or statement material to a false or fraudulent claim for payment and  
3 approval for prescriptions for Zytiga.

4           392. Through the acts described above, Defendants conspired to (a) present, or cause to be  
5 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
6 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
7 Zytiga.

8           393. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
9 were not entitled to be paid by the State of Rhode Island—through any state funded program,  
10 including, without limitation, Medicaid—for Zytiga.

11           394. Through the acts described herein, Defendants knowingly presented, or caused to be  
12 presented, false or fraudulent claims to the State of Rhode Island.

13           395. Relator cannot at this time identify all of the false claims for payment that were caused  
14 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
15 State of Rhode Island. Relator has no control over or dealings with such entities and has no access to  
16 the records in their possession.

17           396. The State of Rhode Island, unaware of the falsity of the records, statements and  
18 claims made or caused to be made by Defendants, paid and continues to pay the claims that the State  
19 of Rhode Island would not have paid but for Defendants' illegal conduct.

20           397. By reason of Defendants' acts, the State of Rhode Island has been damaged, and  
21 continues to be damaged, in substantial amount to be determined at trial.

22           398. Additionally, the State of Rhode Island is entitled to a statutory penalty for each and  
23 every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

24           399. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
25 State of Rhode Island pursuant to R.I. Gen. Laws § 9-1.1-4(b).  
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27  
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**Count XXVII**  
**Tennessee Medicaid False Claims Act**  
**Tenn. Code Ann. §§ 7-5-181 to -185**

400. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

401. This is a claim for treble damages and penalties under the Tennessee Medicaid False Claims Act.

402. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

403. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

404. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

405. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Tennessee—through any state funded program, including, without limitation, Medicaid—for Zytiga.

406. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Tennessee.

407. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Tennessee. Relator has no control over or dealings with such entities and has no access to the records in their possession.





418. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Texas.

419. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Texas. Relator has no control over or dealings with such entities and has no access to the records in their possession.

420. The State of Texas, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Texas would not have paid but for Defendants' illegal conduct.

421. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

422. Additionally, the State of Texas is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

423. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Texas pursuant to Tex. Hum. Res. Code Ann. § 36.101.

**Count XXIX**  
**Vermont False Claims Act**  
**Vt. Stat. Ann. tit. 32, §§ 630-642**

424. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

425. This is a claim for treble damages and penalties under the Vermont False Claims Act.

426. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

1           427. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 made or used a false record or statement material to a false or fraudulent claim for payment and  
3 approval for prescriptions for Zytiga.

4           428. Through the acts described above, Defendants conspired to (a) present, or cause to be  
5 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
6 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
7 Zytiga.

8           429. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
9 were not entitled to be paid by the State of Vermont—through any state funded program, including,  
10 without limitation, Medicaid—for Zytiga.

11           430. Through the acts described herein, Defendants knowingly presented, or caused to be  
12 presented, false or fraudulent claims to the State of Vermont.

13           431. Relator cannot at this time identify all of the false claims for payment that were caused  
14 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
15 State of Vermont. Relator has no control over or dealings with such entities and has no access to the  
16 records in their possession.

17           432. The State of Vermont, unaware of the falsity of the records, statements and claims  
18 made or caused to be made by Defendants, paid and continues to pay the claims that the State of  
19 Vermont would not have paid but for Defendants' illegal conduct.

20           433. By reason of Defendants' acts, the State of Vermont has been damaged, and continues  
21 to be damaged, in substantial amount to be determined at trial.

22           434. Additionally, the State of Vermont is entitled to a statutory penalty for each and every  
23 violation alleged herein to be determined by the Court in accordance with the relevant statutes.

24           435. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
25 State of Vermont pursuant to Vt. Stat. Ann. tit. 32, § 632(b)(1).  
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**Count XXX**  
**Virginia Fraud Against Taxpayers Act**  
**Va. Code Ann. §§ 8.01-216.1 to .19**

436. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

437. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

438. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

439. Through the acts described above, Defendants knowingly, intentionally, and willfully made or used a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

440. Through the acts described above, Defendants conspired to (a) present, or cause to be presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or statement material to a false or fraudulent claim for payment and approval for prescriptions for Zytiga.

441. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the Commonwealth of Virginia—through any state funded program, including, without limitation, Medicaid—for Zytiga.

442. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the Commonwealth of Virginia.

443. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the Commonwealth of Virginia. Relator has no control over or dealings with such entities and has no access to the records in their possession.





453. Because of Defendants' violations the false claims statutes alleged herein, Defendants were not entitled to be paid by the State of Washington—through any state funded program, including, without limitation, Medicaid—for Zytiga.

454. Through the acts described herein, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the State of Washington.

455. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants' conduct. The false claims were presented by numerous separate entities across the State of Washington. Relator has no control over or dealings with such entities and has no access to the records in their possession.

456. The State of Washington, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that the State of Washington would not have paid but for Defendants' illegal conduct.

457. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in substantial amount to be determined at trial.

458. Additionally, the State of Washington is entitled to a statutory penalty for each and every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

459. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the State of Washington pursuant to Wash. Rev. Code § 74.66.050.

**Count XXXII**  
**The District of Columbia False Claims Law**  
**D.C. Code §§ 2-381.01 to .09**

460. Relator realleges and incorporates by reference all foregoing allegations as though fully set forth herein.

461. This is a claim for treble damages and penalties under the District of Columbia False Claims Law.

462. Through the acts described above, Defendants knowingly, intentionally, and willfully presented, or caused to be presented, false or fraudulent claims for payment and approval for prescriptions for Zytiga.

1           463. Through the acts described above, Defendants knowingly, intentionally, and willfully  
2 made or used a false record or statement material to a false or fraudulent claim for payment and  
3 approval for prescriptions for Zytiga.

4           464. Through the acts described above, Defendants conspired to (a) present, or cause to be  
5 presented, false or fraudulent claims for payment and approval; and (b) make or use a false record or  
6 statement material to a false or fraudulent claim for payment and approval for prescriptions for  
7 Zytiga.

8           465. Because of Defendants' violations the false claims statutes alleged herein, Defendants  
9 were not entitled to be paid by the District of Columbia—through any state funded program,  
10 including, without limitation, Medicaid—for Zytiga.

11           466. Through the acts described herein, Defendants knowingly presented, or caused to be  
12 presented, false or fraudulent claims to the District of Columbia.

13           467. Relator cannot at this time identify all of the false claims for payment that were caused  
14 by Defendants' conduct. The false claims were presented by numerous separate entities across the  
15 District of Columbia. Relator has no control over or dealings with such entities and has no access to  
16 the records in their possession.

17           468. The District of Columbia, unaware of the falsity of the records, statements and claims  
18 made or caused to be made by Defendants, paid and continues to pay the claims that District of  
19 Columbia would not have paid but for Defendants' illegal conduct.

20           469. By reason of Defendants' acts, the District of Columbia has been damaged, and  
21 continues to be damaged, in substantial amount to be determined at trial.

22           470. Additionally, the District of Columbia is entitled to a statutory penalty for each and  
23 every violation alleged herein to be determined by the Court in accordance with the relevant statutes.

24           471. Relator has standing as a *qui tam* relator to bring this cause of action on behalf of the  
25 District of Columbia pursuant to D.C. Code § 2-308.15(b)(1).  
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**PRAYER FOR RELIEF**

WHEREFORE, Relator prays for judgment against Defendants as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §§ 3729–3733, and the relevant parts of each statute applicable to the Plaintiff States as set forth above;

B. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$21,916 for each violation of 31 U.S.C. §§ 3729–3733;

C. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of California has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the California False Claims Act, Cal. Gov't Code §§ 12650–12656;

D. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Colorado has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Colorado Medicaid False Claims Act, Colo. Rev. Stat §§ 25.5-4-303.5 to -310;

E. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Connecticut has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Connecticut False Claims Act, Conn. Gen. Stat. §§ 4-274 to -289;

F. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendants' actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the Delaware False Claims and Reporting Act, Del. Code Ann. tit. 6, §§ 1201–1211;

G. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendants' actions, plus a civil



1 penalty for the maximum amount allowed by statute, for each violation of the Florida False Claims  
2 Act, Fla. Stat. §§ 68.081-.09;

3 H. That this Court enter judgment against Defendants in an amount equal to three times  
4 the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil  
5 penalty for the maximum amount allowed by statute, for each violation of the Georgia False  
6 Medicaid Claims Act, Ga. Code Ann. §§ 49-4-168 to -168.6;

7 I. That this Court enter judgment against Defendants in an amount equal to three times  
8 the amount of damages the State of Hawaii has sustained because of Defendants' actions, plus a civil  
9 penalty for the maximum amount allowed by statute, for each violation of the Hawaii False Claims  
10 Act, Haw. Rev. Stat. §§ 661-21 to -31;

11 J. That this Court enter judgment against Defendants in an amount equal to three times  
12 the amount of damages the State of Illinois has sustained because of Defendants' actions, plus a civil  
13 penalty for the maximum amount allowed by statute, for each violation of the Illinois False Claims  
14 Act, 740 Ill. Comp. Stat. 175/1-175/8;

15 K. That this Court enter judgment against Defendants in an amount equal to three times  
16 the amount of damages the State of Indiana has sustained because of Defendants' actions, plus a civil  
17 penalty for the maximum amount allowed by statute, for each violation of the Indiana False Claims  
18 and Whistleblower Protection Act, Ind. Code §§ 5-11-5.5-1 to -18;

19 L. That this Court enter judgment against Defendants in an amount equal to three times  
20 the amount of damages the State of Iowa has sustained because of Defendants' actions, plus a civil  
21 penalty for the maximum amount allowed by statute, for each violation of Iowa False Claims Act,  
22 Iowa Code §§ 685.1-.7;

23 M. That this Court enter judgment against Defendants in an amount equal to three times  
24 the amount of damages the State of Louisiana has sustained because of Defendants' actions, plus a  
25 civil penalty for the maximum amount allowed by statute, for each violation of the Louisiana Medical  
26 Assistance Programs Integrity Law, La. Rev. Stat. Ann. §§ 46:437-:440;

1 N. That this Court enter judgment against Defendants in an amount equal to three times  
2 the amount of damages the State of Maryland has sustained because of Defendants' actions, plus a  
3 civil penalty for the maximum amount allowed by statute, for each violation of the Maryland False  
4 Health Claims Act, Md. Code Ann., Health-Gen. §§ 2-601 to -611;

5 O. That this Court enter judgment against Defendants in an amount equal to three times  
6 the amount of damages Commonwealth of Massachusetts has sustained because of Defendants'  
7 actions, plus a civil penalty for the maximum amount allowed by statute, for each violation of the  
8 Massachusetts False Claims Act, Mass. Gen. Laws ch. 12, §§ 5A-5O;

9 P. That this Court enter judgment against Defendants in an amount equal to three times  
10 the amount of damages the State of Michigan has sustained because of Defendants' actions, plus a  
11 civil penalty for the maximum amount allowed by statute, for each violation of the Michigan  
12 Medicaid False Claims Act, Mich. Comp. Laws. §§ 400.601-.615;

13 Q. That this Court enter judgment against Defendants in an amount equal to three times  
14 the amount of damages the State of Minnesota has sustained because of Defendants' actions, plus a  
15 civil penalty for the maximum amount allowed by statute, for each violation of the Minnesota False  
16 Claims Act, Minn. Stat, §§ 15C.01-.16;

17 R. That this Court enter judgment against Defendants in an amount equal to three times  
18 the amount of damages the State of Montana has sustained because of Defendants' actions, plus a  
19 civil penalty for the maximum amount allowed by statute, for each violation of the Montana False  
20 Claims Act, Mont. Code Ann. §§ 17-8-401 to -413;

21 S. That this Court enter judgment against Defendants in an amount equal to three times  
22 the amount of damages the State of Nevada has sustained because of Defendants' actions, plus a civil  
23 penalty for the maximum amount allowed by statute, for each violation of the Nevada statute  
24 concerning Submission of False Claims to State or Local Government, Nev. Rev. Stat. §§ 357.010-  
25 .250;

26 T. That this Court enter judgment against Defendants in an amount equal to three times  
27 the amount of damages the State of Hampshire has sustained because of Defendants' actions, plus a  
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1 civil penalty for the maximum amount allowed by statute, for each violation of the New Hampshire  
 2 Health Care False Claims Law, N.H. Rev. Stat. Ann. §§ 167:58 to :61-e;

3 U. That this Court enter judgment against Defendants in an amount equal to three times  
 4 the amount of damages the State of New Jersey has sustained because of Defendants' actions, plus a  
 5 civil penalty for the maximum amount allowed by statute, for each violation of the New Jersey False  
 6 Claims Act, N.J. Stat. Ann. §§ 2A:32C-1 to -18;

7 V. That this Court enter judgment against Defendants in an amount equal to three times  
 8 the amount of damages the State of New Mexico has sustained because of Defendants' actions, plus  
 9 a civil penalty for the maximum amount allowed by statute, for each violation of the New Mexico  
 10 Medicaid False Claims Act, N.M. Stat. Ann. §§ 27-14-1 to -15; and the New Mexico Fraud Against  
 11 Taxpayers Act, N.M. Stat. Ann. §§ 44-9-1 to -14.

12 W. That this Court enter judgment against Defendants in an amount equal to three times  
 13 the amount of damages the State of New York has sustained because of Defendants' actions, plus a  
 14 civil penalty for the maximum amount allowed by statute, for each violation of the New York False  
 15 Claims Act, N.Y. State Fin. Law §§ 187-194;

16 X. That this Court enter judgment against Defendants in an amount equal to three times  
 17 the amount of damages the State of North Carolina has sustained because of Defendants' actions,  
 18 plus a civil penalty for the maximum amount allowed by statute, for each violation of the North  
 19 Carolina False Claims Act, N.C. Gen. Stat. §§ 1-605 to -618;

20 Y. That this Court enter judgment against Defendants in an amount equal to three times  
 21 the amount of damages the State of Oklahoma has sustained because of Defendants' actions, plus a  
 22 civil penalty for the maximum amount allowed by statute, for each violation of the Oklahoma  
 23 Medicaid False Claims Act, Okla. Stat. tit. 63, §§ 5053-5053.7;

24 Z. That this Court enter judgment against Defendants in an amount equal to three times  
 25 the amount of damages the State of Rhode Island has sustained because of Defendants' actions, plus  
 26 a civil penalty for the maximum amount allowed by statute, for each violation of the Rhode Island  
 27 False Claims Act, R.I. Gen. Laws §§ 9-1.1-1 to -9;

1 AA. That this Court enter judgment against Defendants in an amount equal to three times  
 2 the amount of damages the State of Tennessee has sustained because of Defendants' actions, plus a  
 3 civil penalty for the maximum amount allowed by statute, for each violation of the Tennessee  
 4 Medicaid False Claims Act, Tenn. Code Ann. §§ 71-5-181 to -185;

5 BB. That this Court enter judgment against Defendants in an amount equal to two times  
 6 the amount of damages the State of Texas has sustained because of Defendants' actions, plus a civil  
 7 penalty for the maximum amount allowed by statute, for each violation of the Texas Medicaid Fraud  
 8 Prevention Law, Tex. Hum. Res. Code Ann. §§ 36.001-.132;

9 CC. That this Court enter judgment against Defendants in an amount equal to three times  
 10 the amount of damages the State of Vermont has sustained because of Defendants' actions, plus a  
 11 civil penalty for the maximum amount allowed by statute, for each violation of the Vermont False  
 12 Claims Act, Vt. Stat. Ann. tit. 32, §§ 630-642;

13 DD. That this Court enter judgment against Defendants in an amount equal to three times  
 14 the amount of damages the Commonwealth of Virginia has sustained because of Defendants' actions,  
 15 plus a civil penalty for the maximum amount allowed by statute, for each violation of the Virginia  
 16 Fraud Against Taxpayers Act, Va. Code Ann. §§ 8.01-216.1 to .19;

17 EE. That this Court enter judgment against Defendants in an amount equal to three times  
 18 the amount of damages the State of Washington has sustained because of Defendants' actions, plus a  
 19 civil penalty for the maximum amount allowed by statute, for each violation of the Washington State  
 20 Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.005-.130;

21 FF. That this Court enter judgment against Defendants in an amount equal to three times  
 22 the amount of damages the District of Columbia has sustained because of Defendants' actions, plus a  
 23 civil penalty for the maximum amount allowed by statute, for each violation of the District of  
 24 Columbia False Claims Act, D.C. Code §§ 2-381.01 to .09;

25 GG. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C.  
 26 § 3730(d), and the relevant provisions of each statute applicable to the Plaintiff States as set forth  
 27 above;  
 28



- 1 HH. That Relator be awarded all costs of this action;  
2 II. That the Relator be awarded reasonable attorneys' fees; and  
3 JJ. That Relator recover such further and other relief as the Court deems just and proper.

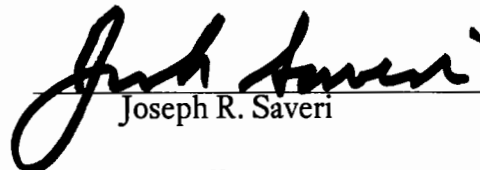
4 **DEMAND FOR JURY TRIAL**

5 Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial  
6 by jury.

7 Dated: December 21, 2017

8 Joseph R. Saveri (State Bar No. 130064)  
9 Nicomedes Sy Herrera (State Bar No. 275332)  
10 Jiamie Chen (*pro hac vice* appl. to be submitted)  
11 Kevin Rayhill (State Bar No. 267496)  
12 Kyla Gibboney (State Bar No. 301441)  
13 JOSEPH SAVERI LAW FIRM, INC.  
14 601 California Street, Suite 1000  
15 San Francisco, California 94108  
16 Telephone: (415) 500-6800  
17 Facsimile: (415) 395-9940

18 By:

19   
20 Joseph R. Saveri

21 *Attorneys for Plaintiffs*

22 United States of America; the States of California,  
23 Colorado, Connecticut, Delaware, Florida, Georgia,  
24 Hawaii, Illinois, Indiana, Iowa, Louisiana, Maryland,  
25 Michigan, Minnesota, Montana, Nevada, New  
26 Hampshire, New Jersey, New Mexico, New York,  
27 North Carolina, Oklahoma, Rhode Island, Tennessee,  
28 Texas, Vermont, and Washington; the  
Commonwealths of Massachusetts and Virginia; and  
the District of Columbia, *ex rel.* Zachary Silbersher